

IV. Remarks**A. Amendments to the Specification**

Paragraph 1 of the Specification has been amended to recite that the parent patent 6,708,057, which was incorporated by reference in its entirety into this application, claims priority to U.S. Provisional Patent Application No. 60/331,839.

B. Claim Rejection under 35 U.S.C. §112

The Action rejects claims 31 and 42 as being indefinite because “said clinical study” lacks antecedent basis. Claims 31 and 42 have been amended to correct this informality.

C. Allowable Subject Matter

The Applicant is grateful to the Examiner for allowing claims 6-8, 10, 16-18, 45 and 46 and for recognizing the allowable subject matter set forth in claims 43 and 44.

D. Rejection under 35 U.S.C. §102**1. Claim 1-5 and 11-15**

The Action rejects claims 1-5 and 11-15 as being anticipated by U.S. Patent No. 6,603,464 to Rabin.

Claim 1 is directed to a method of processing an electrocardiogram (ECG). Digital parameter data for a clinical study are received. The digital parameter data represent demographic data to be collected for ECGs associated with said clinical study and rules associated with said clinical study. Claim 1 has been amended to recite the step of traversing collected demographic data against digital parameter data to identify problems with the collected demographic data. Claim 1 also recites the step of automatically generating a query when a problem is identified with the collected demographic data based on the traversing step, where the query elicits resolution of the problem.

It is submitted that Rabin does not teach a computer implemented method that traverses collected demographic data against digital parameter data to identify problems with the collected data and then automatically generate a query when a problem is identified with the collected demographic data based on the traversing step, where the query elicits resolution of the problem.

With respect to the recited query generation feature, the Examiner states that Rabin teaches that "when a problem is identified with collected demographic information, a query is automatically sent to staff in order to elicit resolution of the problem (Col. 8, lines 46-67)." The Applicant respectfully disagrees with this interpretation of Rabin's disclosure. Rabin discloses that collected information can be sent to a recipient by e-mail fax, etc. (Col. 8, Lines 44-52). "Once [this information is] received by the recipient, the recipient can process the information and prepare an appropriate response . . . Should the recipient have a question or identify a problem (e.g., potential drug interaction), a response can be sent electronically back to the computer." (Col. 8, Lines 52-59) (emphasis added). It is clear from Rabin's disclosure that the recipient manually reviews data sent to the individual and manually discovers any problems with the data. The recipient then communicates back to a computer to note the problem. This manual review and problem identification process is not a computer implemented method as claimed that performs the following steps:

- (i) **traversing collected demographic data against the digital parameter data to identify problems with said collected demographic data; and**
- (ii) **automatically generating a query when a problem is identified with said collected demographic data based upon the traversing step, said query eliciting resolution of said problem.**

For at least these reasons, it is submitted that independent claim 1 is not anticipated by Rabin and is allowable thereover.

Claim 5 has been amended to be consistent with the amendments to claim 1. Claims 2-5 depend from claim 1 and are, therefore, also not anticipated by the cited reference.

Independent claim 11 has been amended in a manner similar to that for claim 1. Dependent claim 15 has been amended in a manner consistent with the amendments to claim 11. It is submitted that independent claim 11 is allowable for reasons analogous to those argued above in connection with claim 1. Claims 12-15 depend from claim 11 and are, therefore, also allowable over the cited reference.

2. Claims 20-42 and 47-54

The Action rejects claims 20-42 and 47-54 as being anticipated by U.S. Patent Publication No. 2002/0172404 to Badilini.

Independent claim 20 has been canceled without prejudice in order to simplify the issues for discussion herein. The rejection of claim 20 is moot.

Independent claim 21 has been amended to better recite that the digital annotation data is recorded separate or apart from the ECG tracing image. When retrieved, the retrieved digital annotation data is combined with digital ECG data to develop an annotated ECG tracing image that shows the markings corresponding to the interval points identified by the user. The annotated ECG tracing image (i.e., the image developed from the retrieved annotation data combined with this digital ECG data) is then displayed on a display.

Claim 21 has been amended to emphasize that the annotation data is recorded apart from the ECG image data for later retrieval and combination with the ECG data to display an annotated ECG image. It is important that the annotation data be stored separately and then later used to create the annotated image because, for example, a reviewing physician or a regulatory agency may want to review the native ECG image data without annotation. This approach allows for review without the bias of the annotations but also preserves the ability to review an annotated image if desired because the annotation data relating to identified intervals has been recorded.

It is submitted that Badilini does not teach or suggest a method where digital annotation data representing said identified interval points for said at least one interval are recorded apart from said ECG tracing image and then retrieved for combination with digital ECG data to develop an annotated ECG image for display. In the Action, the Examiner points to paragraph 60 of Badilini. Paragraph 60 of Badilini discloses that its system creates a "bitmap" file that includes the ECG wave and tangent, Q, and interval lines. A bitmap file includes data that correspond bit for bit with an image displayed on a screen. As such, this file cannot record annotation data apart from the ECG image as claimed. It follows that Badilini's system also cannot develop or display an annotated ECG image from such retrieved, separately recorded annotation data.

For at least these reasons, it is submitted that claim 21 is not anticipated by Badilini and is allowable thereover. Dependent claim 29 has been amended consistent with the amendments to claim 21. Claims 22-31 and 47-50 depend from claim 21 and are, therefore, also allowable over the cited reference.

Independent claim 32 has been amended in a manner similar to claim 21 and is allowable for reasons analogous thereto. Claim 40 has been amended in a manner consistent with the amendments to claim 32. Claims 33-42 and 51-54 depend from claim 32 and are, therefore, also allowable over the cited reference.

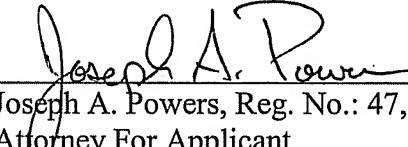
V. Conclusion

In view of the foregoing remarks and amendments, Applicant submits that this application is in condition for allowance at an early date, which action is earnestly solicited.

The Commissioner for Patents is hereby authorized to charge any additional fees or credit any excess payment that may be associated with this communication to deposit account 04-1679.

Respectfully submitted,

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